

## REMARKS

This reply is in response to a communication with mail date of 04/30/2008, which is titled as an Office Action. This communication comes approximately 6 months after an Appeal Brief was filed by Applicant in response to a Final Action of 03/06/2007 rejecting all claims and an Advisory Action of 06/18/2007 maintaining the rejection of all claims.

It is respectfully submitted that this communication is not a proper action. The options available to the Examiner after the filing of an Appeal Brief are (1) to furnish an Examiner's Answer to the Appeal Brief within two months of receipt of the Appeal Brief (see MPEP 1207) or (2) to reopen prosecution to enter a new ground of rejection with approval from the supervisory patent examiner (see MPEP 1207.04).

The Examiner has failed to provide an Examiner's Answer to the Appeal Brief, as the Office Action of 04/30/2008 clearly fails to meet the requirements set forth in MPEP 1207.02 regarding the required contents of an Examiner's Answer.

The Examiner has likewise failed to properly reopen prosecution, as there is no evidence in the Office Action of 04/30/2008 or in the PAIR online database that permission was sought from or that the supervisory patent examiner has approved reopening prosecution to enter a new ground of rejection.

The Examiner states in Section 1 (entitled Response to Appeal Brief) of the current Office Action that "Applicant's request for reconsideration of the finality of the rejection of the last Office Action is persuasive and, therefore, the finality of that action is withdrawn." Applicant made no such request in the Appeal Brief. This request was made in a Response After Final Rejection dated 05/03/2007, to which the Examiner responded with the Advisory Action of 06/18/2007. In that Advisory Action the Examiner failed to withdraw the finality of the

03/06/2007 Office Action. Because of this, Applicant filed the Notice of Appeal and the Appeal Brief.

As to the purported new grounds of rejection, the combination of Morita and Stanners fails to make obvious the invention as claimed.

Independent claim 1 requires “an interior axially projecting post disposed within said opening of said cap, whereby said needle piercing tip is embedded with said interior axially projecting post in said pre-use configuration” and further requires that “in a post-use configuration ... said cap is mounted onto said lancet body with said opening of said cap receiving said lancet distal end and at least a portion of said piercing tip embedded within said axially projecting post.”

Morita lacks an interior projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated recess 42 disposed opposite to the opening 28 (col. 6, line 19). The piercing tip 16 of Morita is not disposed within the opening 28 in the pre-use configuration, but is instead disposed within the body of the cap itself or within a flange member that is not an interior axially projecting post. In the post-use configuration with the cap 14 mounted onto the lancet body 20, the piercing tip 16 of Morita extends into the recess 42 and is embedded in the closed bottom 30. The structure of Morita is the opposite of that of claim 1, in that the recess 42 produces a lesser thickness to receive the needle, whereas the post of the claim produces a greater thickness. Thus, Morita does not anticipate the elements as set forth in lines 11-15.

Stanners shows in Figures 26-28 the presence of a rubber plug 141 in the needle cover 140. Element 141 is exactly what it is defined to be in the '288 patent - a plug, not an “interior

axially projecting post” (element 46 of the application at hand) as required by claim 1 at hand. Combining the teaching of Stanners with Morita would simply result in a device wherein the recess 42 of Morita is not present (please see the attached illustrations). There is nothing in the known prior art that would teach, suggest, motivate or by common sense cause one of ordinary skill in the art to provide Morita with an axially projecting post. By providing a post member instead of a full plug of sufficient thickness to retain the needle tip, a significantly smaller volume of material is required to manufacture the product. With a product that numbers in millions of units, the savings are substantial.

Independent claim 5 requires a cap connected to the lancet body with the “piercing tip embedded therein by a frangible junction” (lines 3-4), with the “cap comprising an opening facing in the distal direction away from said lancet body” (lines 4-5). As illustrated in Figures 3, 4, 7, 8 and 11 of Morita, when the piercing tip 16 is embedded in the cap 14, the opening 28 does not face in the distal direction away from the lancet body. Instead the opening 28 faces in the lateral or radial direction transverse to the proximal-distal direction axis. Independent claim 11 contains language similar to that quoted above in claim 5, and the same rationale applies that Morita neither alone nor in combination with Stanners makes obvious the claimed elements as set forth. The teaching of Stanners adds nothing to Morita in this regard.

Independent claim 18 requires a “cap being generally cylindrical and coaxially aligned with said shaft prior to separation of said frangible junction and removal” (line 7-9). In Morita, the cap is not coaxially aligned with the needle shaft prior to its removal from the lancet body.

In Stanners, there is no frangible junction. Therefore, the combination of Morita and Stanners does not make obvious the invention as claimed.

It is respectfully submitted that the claims as presented are patentable over the cited prior art, on the basis of the above remarks, and reconsideration and subsequent passage for allowance is hereby requested.

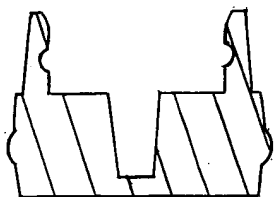
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas C. Saitta", written in a cursive style.

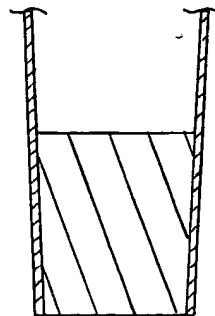
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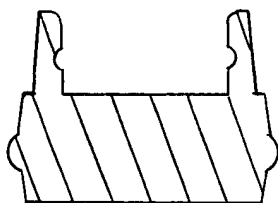
MORITA



STANNERS



COMBINED MORITA AND STANNERS



INVENTION AS CLAIMED

